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October 31, 1986

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Patent Section
Law Department
ICI Americas Inc.
Concord Pike & New Murphy Road
Wilmington, DE 19897

RE: Patent Term Extension
Application for
U.S. Patent No. 4,263,432
Issued April 21, 1981

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,263,432 issued April 21, 1981, is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be 615 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register on April 8, 1986, as follows:

$$\begin{aligned}\text{Period} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (839) + 707 \\ &= 1127 \text{ days}\end{aligned}$$

Since the regulatory review period took place after the patent issue date and there was no determination of a lack of due diligence, the entire period has been considered. The exception of 35 USC 156(c)(3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (December 27, 1985) when added to the period of extension calculated above (1127) cannot exceed 14 years. The period of extension is thus limited to December 27, 1999, by operation of 35 USC 156(c)(3). Since the patent term of seventeen (17) years (35 USC 154) would expire on April 21, 1998, the period of extension is the number of days to extend the term of the patent to December 27, 1999, or 615 days. The limitations of 35 USC 156(g)(4) do not operate to reduce the period of extension determined above.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of U.S. Patent No. 4,263,432 may be made if filed within one (1) month of the date of this notice. In the absence of such request, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,263,432, a certificate of extension, under seal, for a period of 615 days. The rights derived from the patent during the period during which the patent is extended are defined in 35 USC 156(b).

C.E. Van Horn

Charles E. Van Horn, Director
Patent Examining Group 120

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs
Food & Drug Administration
5600 Fishers Lane
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RE: Cefotan
FDA Docket #86E-0098